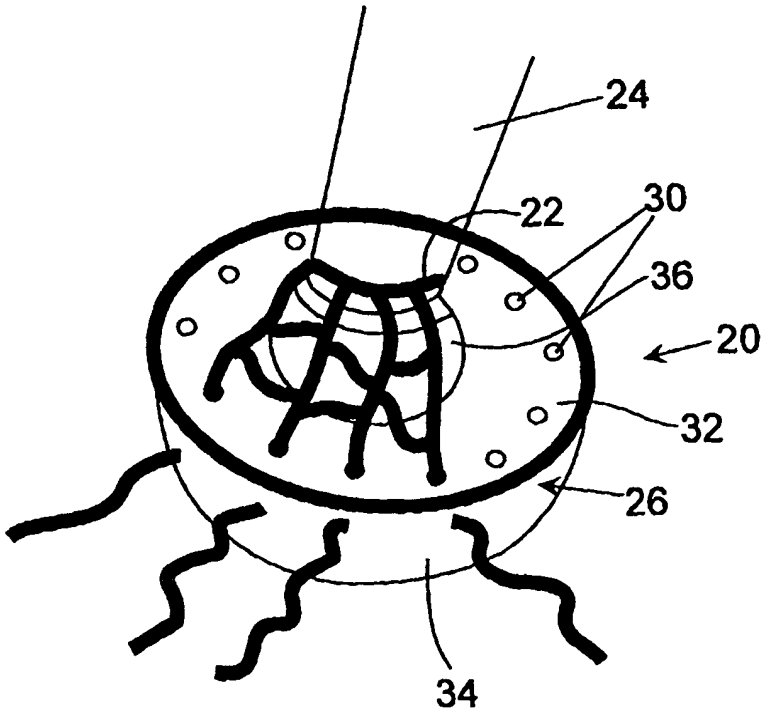


PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/34, 2/36	A1	(11) International Publication Number: WO 99/59505 (43) International Publication Date: 25 November 1999 (25.11.99)
<p>(21) International Application Number: PCT/US99/10994</p> <p>(22) International Filing Date: 19 May 1999 (19.05.99)</p> <p>(30) Priority Data: 60/085,975 19 May 1998 (19.05.98) US</p> <p>(71)(72) Applicant and Inventor: McGANN, William, A. [US/US]; 55 20th Avenue, San Francisco, CA 94121 (US).</p> <p>(74) Agent: MEYER, Sheldon, R.; Fliesler, Dubb, Meyer and Lovejoy LLP, Suite 400, Four Embarcadero Center, San Francisco, CA 94111-4156 (US).</p>		<p>(81) Designated States: JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published With international search report.</p>
<p>(54) Title: THE NET SEMICONSTRAINED DEVICE FOR TOTAL HIP REPLACEMENT STABILITY</p> <p>(57) Abstract</p> <p>An apparatus and method for hip replacement stability includes a connector which is adapted to be connected between at least one of an acetabular cup (26) or a component of an acetabular cup (26) or the adjacent bone (28), and at least one of a replacement femur or a femur. The connector is flexible and allows for uninhibited movement between an acetabular cup (26) and replacement femur (24) up to a limit in order to prevent dislocation. The connector is in one embodiment comprised of a net (20). The method of the invention for preventing dislocation between an acetabular cup (26) and replacement femur (24) includes the steps of securing the connector to at least one of an acetabular cup (26), or a component thereof, or bone (28) located adjacent to an acetabular cup (26), and securing the connector to at least one of a replacement femur (24) or a femur.</p> 		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LJ	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

THE NET SEMICONSTRAINED DEVICE FOR TOTAL HIP REPLACEMENT STABILITY

5 The application claims the benefit of U.S. Provisional Application No.
60/085,975, filed May 19, 1998

Field of the Invention:

10 The present invention is directed to hip replacement systems
and components thereof.

Background of the Invention:

15 Total hip replacement is considered the most successful
orthopaedic surgical procedure ever devised. Its success has now
spanned three decades. There are now approximately 120,000 hip
replacements performed in the U.S. each year. About one-third of the
operations performed are for revision replacement of previously
implanted prosthetic hips. The main cause of revision is for aseptic
loosening. Another reason for revision is dislocation of the
components. Dislocation continues to be a problem in total hip
20 replacement. Every surgeon who performs this operation has this
complication, no matter how experienced he or she is with total hip
replacement. The incidence of dislocation varies widely in the
community. Most experienced surgeons expect less than a 3%
incidence. Some community surgeons are known to have as high as
25 30% dislocation rate. Dislocations are proven to be associated with
(i) the type of approach, posterior being the most common -- 90%, and
(ii) whether the case is a revision (three times the incidence over
primary replacements). About half of the dislocations occur in the first
month after the procedure. The remainder of the dislocations occur
30 over the span of many years. A dislocation can occur at any time in

- 2 -

the lifetime of the arthroplasty. It is evident that dislocation remains a problem complication in the most successful orthopaedic procedure ever devised.

Attempts have been made to make the hip replacement operation more stable and thus reduce the incidence of dislocation. To preserve soft tissue attachments posteriorly, the surgical approach has been changed. The "direct lateral approach" has been utilized in the joint replacement, but residual pain, limp, and heterotopic ossification have tempered its use. It is not well proven that the incidence has been dramatically affected despite this change in the approach. Recently, unpublished reports have demonstrated an improved dislocation rate through the reattachment of soft tissues in conjunction with the posterior approach. This technique remains to be proven and additional study is needed. The posterior soft-tissue techniques do not address revision operations, since the soft tissues are deficient or absent in revision cases.

Modification of the components has also been undertaken to try and make the arthroplasty more stable. The use of a locking mechanism between the femoral ball and the acetabular socket has been fraught with problems. This so-called "constrained" socket fails early because of high stresses arising from impingement between the socket and femoral neck. This may cause the socket to pull out from the bone attachment in the pelvis, or dislodge the ring lock holding the devices together. Another modification is the simple addition of a buildup of the polyethylene rim. This modification does not appear to influence the dislocation rate in clinical studies. This is probably because of the reduction of a "safe zone" before impingement occurs between the femoral neck and the rim of the polyethylene socket. On the femoral side, attempts at enlarging the diameter of the femoral head had not influenced the rate of dislocation. Enlarging the femoral

- 3 -

head has been unpopular largely because of the problem of increased polyethylene wear seen with large diameter heads.

Summary of the Invention:

5 The present invention is directed to overcome some of the disadvantages of the prior art. In particular, the present invention is directed toward an apparatus and method for preventing dislocation between an acetabular cup and a replacement femur.

10 In one aspect of the invention, a device is provided for hip replacement stability. The hip replacement uses an acetabular cup implantable into an adjacent bone and a replacement femur implantable into a femur. The device of the invention includes a connector which is adapted to connect to (1) at least one of an acetabular cup, or a component of an acetabular cup, or the adjacent bone, and (2) at least
15 one of a replacement femur or a femur.

 The connector is flexible.

 In another aspect of the invention, the connector is adapted for allowing uninhibited movement between an acetabular cup and a replacement femur up to a limit.

20 In yet a further aspect of the invention, a connector is adapted for preventing a replacement femur from becoming dislocated from an acetabular cup.

 In yet a further aspect of the invention, a connector is comprised of a net.

25 In still a further aspect of the invention, a method is provided for preventing dislocation between an acetabular cup and replacement femur comprising the steps of securing a connector to at least one of an acetabular cup, or a component thereof, or a bone located adjacent to an acetabular cup and securing a connector to at least one of the
30 replacement femur or a femur.

- 4 -

In another aspect of the invention, a method is provided for preventing dislocation which method includes implanting an acetabular cup or component thereof which has selectively secured thereto a connector and selectively securing the connector to one of a replacement femur or a femur.

Other aspects and objects of the invention can be obtained through a review of the specification of the claims and the figures.

Brief Description of the Figures:

Fig. 1 depicts a schematic drawing of an embodiment of a connector of the invention.

Fig. 2 depicts a figure similar to Fig. 1 with the connector of this embodiment attached through holes of the acetabular cup.

Fig. 3 depicts a side view of the embodiment of Fig. 1.

Figs. 4a, 4b, and 4c demonstrate various methods whereby an embodiment of the invention can be connected to any one of or a combination of the adjacent bone, or the acetabular cup, or components of the acetabular cup including the liner and the metal shelf.

Fig. 5 depicts the various regions where the connector of the invention can be connected to the acetabular cup.

Fig. 6 depicts an embodiment of the invention where the connector is connected to the femur.

Detailed Description of a Preferred Embodiment of the Invention:

The net of the present invention addresses the problem of dislocation in a new way. It effectively reinforces the total hip replacement by providing tension against the specific forces that lead to dislocation.

- 5 -

Fig. 1 depicts a schematic diagram of one variation of the net device 20 of the invention. The net device 20 has a ring 22 which secures the net 20 about the replacement femoral neck 24. The net 20 then is attached to the acetabular cup 26 or the bone 28 into which the acetabular cup 26 is implanted. In this embodiment, the net 20 is comprised of a polyethylene material. However, it is to be understood that other materials such as by way of example only, suture materials can be used and be within the spirit and scope of the invention.

10 This flexible connecting material essentially mimics the normal soft tissue capsule of the hip joint. Importantly, as in the normal hip, the tension is only present at specific positions of the hip joint, and only comes into play when it is needed. During normal activities, the net device 20 is at rest, and is not stressed. This principle is much like
15 the seatbelt in an automobile, that is called into use only when it is required. In the case of a joint replacement which may have a decade or more of use, this factor of only temporary use will allow the device to span many years. The crucial period of usefulness will be in the early postoperative period when the soft tissues are in their healing
20 phase, and are thus at their weakest state. For revision operations, which have limited, or absent soft-tissue response to healing, the net device 20 may be more important for the life of the implant. Adding a biological growth material to the net to stimulate the regrowth of living tissue may restore the biologic stability to the hip replacement,
25 and minimize the utilization of the inert portion of the net device 20 over time.

Fig. 2 depicts the net device 20 attached through holes 30 in the acetabular cup 26. The holes 30 are preferably pre-drilled in the insert 32 of the cup 26. As is known in the art, the insert 32 fits into
30 a shell 34 which is secured to the bone of the patient.

- 6 -

The net can be either pre-set, or tensioned intraoperatively. The advantage of intraoperative tensioning, is to provide specific tension at hip positions that are at risk for dislocation. The position of risk for the more common posterior dislocation is where the hip is (i) flexed, (ii) internally rotated, and (iii) adducted. The number and location of the attachment points of the net 20 to the cup 26 may vary according to the needs of the surgeon. The connections to the socket can be utilized over the posterior, superior, or anterior margin as indicated to correspond to the instability at risk (lack of soft tissue encapsulating the ball and socket joint). Posterior instability generally occur about 90% of the time. As can be seen in Fig. 5, the posterior margin is from about 6:00 to about 12:00 o'clock, the superior margin from about 9:00 to about 3:00 o'clock, and the anterior margin is from about 12:00 to about 6:00 o'clock. Thus, the net 20 can be "called into action" where specifically needed as determined by the surgeon.

In other words, the cup 26 is pre-drilled with holes 30 about the exterior peripheral lip of the cup 26. Only the holes needed to obtain the desired restraint are used to secure the net 20. Further, the length of the strands of the net are adjacent and tied off as appropriate, after the strands are fed through the holes 30. Thus, the net 20 can be positioned where the greatest instability is to provide tension in order to prevent hip dislocation.

The net 20 can be used in both primary and revision total hip procedures. The advantage in revision procedures is noted especially in cases of recurrent dislocation of the hip, where the metal acetabular shell 34 is well fixed to the bone by bone ingrowth. When the metal acetabular shell 34 is well-fixed in the bone, the acetabular liner or insert 32 can be revised with the incorporation of the net 20. Providing the locking mechanism the shell is secure, the new liner 32 with the net 20 can be simply inserted, and the femoral ring 22

- 7 -

attached to the femoral neck, or Morse taper. The net 20 will then provide a mechanism to secure the femoral head 36 in the acetabular cup 26 and allow proper fibrous healing to take place without the risk of dislocation. The net 20 may also eliminate the need for costly external bracing of the limb during the postoperative period. If an insufficient locking mechanism is found between the metal shell 34 and the polyethylene liner 32, then the net 20 can be anchored to the acetabular bone 28 instead of the shell 34 or insert 32.

Also, the femoral side of the net can also be directly attached to the femoral bone 38 if indicated (Fig. 4a and Fig. 6) instead of using net ring 22.

In primary cases of total hip replacement, where the metal shell 34 is not ingrown, the net 20 can be attached to the acetabular bone 28 instead of the acetabular cup 26. This may be necessary since the metal shell 34 may not be fully secured in the acetabular bone 28 for a few months after its insertion. This early period is the critical time to prevent dislocations from occurring. The metal shell 34 may be press-fitted in place, or may be secured with fixation screws. In some situations, especially with exceptional fixation and quality bone, this may be enough to utilize the net attached to the insert or liner 32 of the cup 26. In cases where bone attachment is necessary, drills may be required to facilitate the tunneling of the net through the posterior wall of the acetabulum.

Fig. 3 depicts how the net 20 tightens up to prevent the hip from dislocating in the direction 40 when the femur is moving in the direction 42.

As can be seen in Figs. 4a, 4b, and 4c, the net 20 can be received (i) through the bone, or (ii) through the polyethylene liner shell and bone or (iii) through the polyethylene liner.

Industrial Applicability:

Based on the above, it can be seen that the present invention prevents dislocation of a replacement femur from an acetabular cup. Such prevention greatly increases the success rate and stability of hip
5 implants.

Other features, aspects and objects of the invention can be obtained from a review of the figures and the claims.

It is to be understood that other embodiments of the invention can be developed and fall within the spirit and scope of the invention
10 and claims.

- 9 -

I claim:

1. A device for hip replacement stability which hip replacement uses an acetabular cup implantable into adjacent bone and
5 a replacement femur implantable into a femur, said device comprising:
a connector which is adapted to be connected to (1) at least one of an acetabular cup, or a component of an acetabular cup, or the adjacent bone, and (2) at least one of a replacement femur or a femur.
- 10 2. The device of claim 1 wherein:
said connector is flexible.
3. The device of claim 1 wherein:
said connector is adapted for allowing uninhibited movement
15 between an acetabular cup and a replacement femur up to a limit.
4. The device of claim 1 wherein:
said connector is adapted for preventing a replacement femur
from becoming dislocated from an acetabular cup.
20
5. The device of claim 1 wherein:
said connector is comprised of a net.
6. The device of claim 1 wherein:
25 said connector is comprised of a plurality of tethers.
7. The device of claim 1 wherein:
said connector is comprised of polyethylene.

- 10 -

8. The device of claim 1 wherein:

said connector is adapted to be connected around a neck of a replacement femur.

5 9. The device of claim 1 wherein:

a biological growth material is added to the connector.

10. The device of claim 1 wherein:

the connector is adapted to be received through holes provided
10 in an acetabular cup or a shell or liner component of an acetabular cup.

11. The device of claim 1 wherein:

the connector is adapted to be connected to at least one of the
posterior margin, the superior margin or the anterior margin of an
15 acetabular cup or the adjacent bone.

12. The device of claim 1 wherein:

the length of the connector can be adjusted as is appropriate.

20 13. A device for hip replacement stability which hip replacement uses an acetabular cup implantable into adjacent bone and a replacement femur implantable into a femur, said device comprising:

a flexible connector which can prevent dislocation between the replacement femur and the acetabular cup and which is adapted to be
25 connected to (1) at least one of an acetabular cup, or a component of an acetabular cup, or the adjacent bone, and (2) at least one of a replacement femur or a femur.

- 11 -

14. The device of claim 13 wherein:

said connector is adapted to be connected around a neck of a replacement femur.

5 15. The device of claim 13 wherein:

said connector has a ring which is adapted to be connected around a neck of a replacement femur.

10 16. A method for preventing dislocation between an acetabular cup and a replacement femur comprising the steps of:

securing a connector to at least one of an acetabular cup, or a component thereof, or bone located adjacent to an acetabular cup; and

securing the connector to at least one of a replacement femur or a femur.

15

17. The method of claim 16 including the step of:
adjusting the length of the connector .

20 18. A method for preventing dislocation between an acetabular cup and a replacement femur comprising the steps of:

implanting an acetabular cup or component thereof which has secured thereto a connector; and

securing the connector to one of a replacement femur or a femur.

25

19. The method of claim 18 including the step of:
adjusting the length of the connector.

- 12 -

20. The method of claim 18 including the step of:
wherein said securing step includes securing the connector
around the neck of a replacement femur.

5 21. A hip replacement system comprising:
an acetabular cup or component thereof;
a replacement femur;
a connector which is designed to be connected to (1) at least
one of an acetabular cup, or a component of an acetabular cup, or the
10 adjacent bone, and (2) at least one of a replacement femur or a femur.

22. A method of preventing dislocation between an acetabular
cup and a replacement femur comprising the steps of:
using either (1) an acetabular cup or a component thereof, or (2)
15 a replacement femur, at least one of which has pre-connected thereto
a connector;
implanting the acetabular cup or component thereof; and
securing the connector to the other of (1) the acetabular cup, or
component thereof, or adjacent bone, or (2) a replacement femur or
20 adjacent bone.

1/6

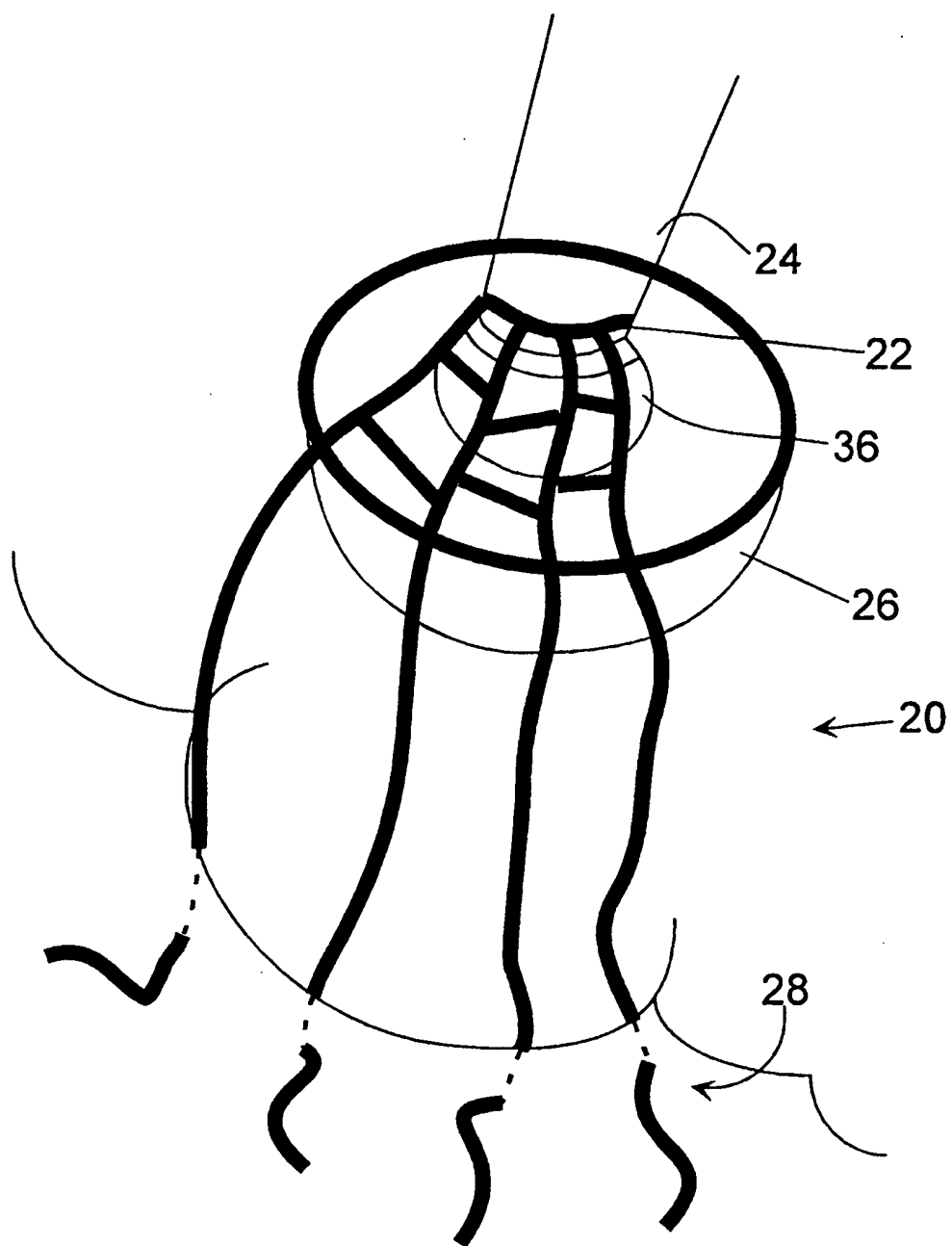


Fig. 1

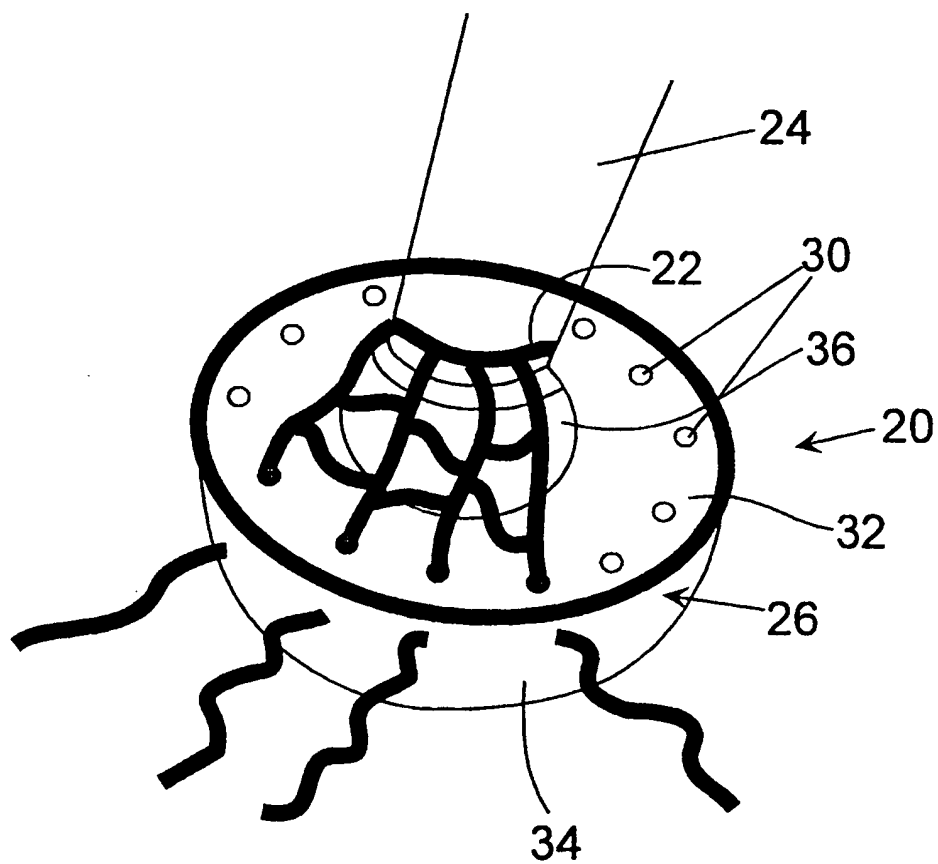


Fig. 2

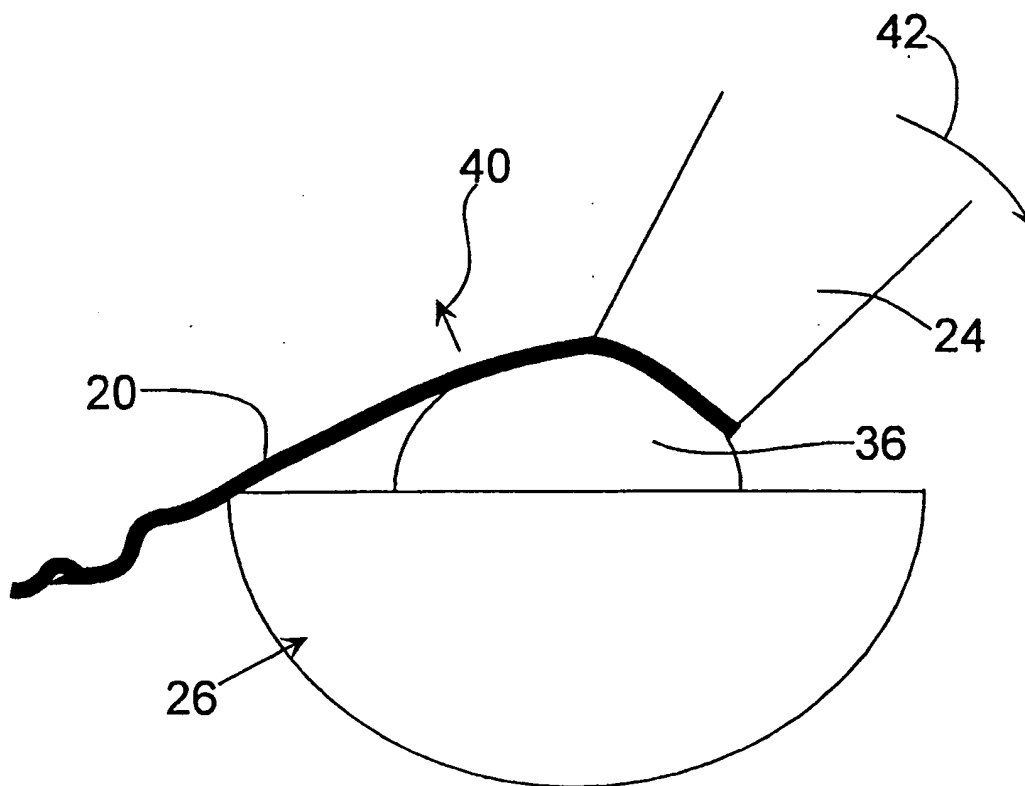


Fig. 3

Net connected
directly to bone

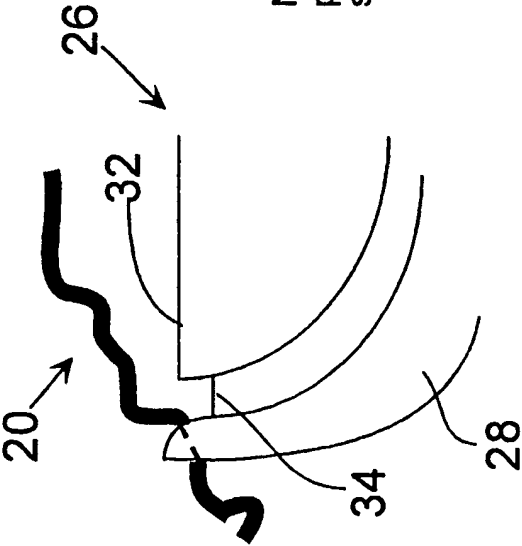


Fig. 4a

Net connected through
polyethylene liner, metal
shell, and bone

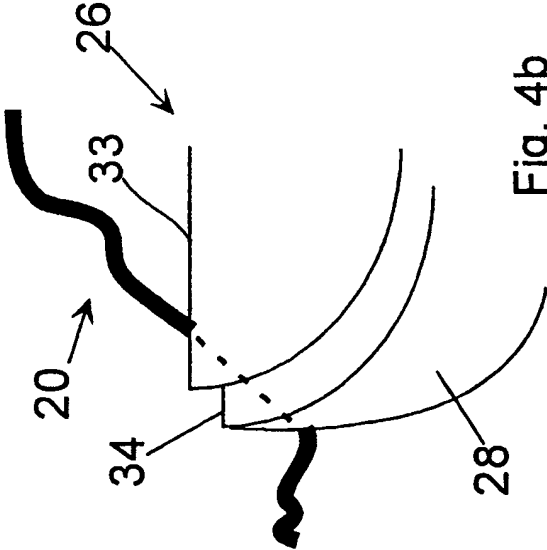


Fig. 4b

Net connected through
polyethylene liner.

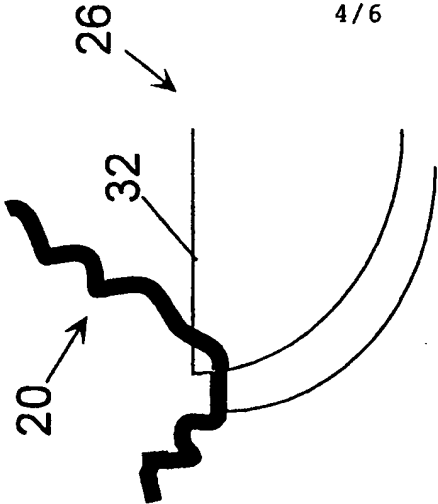


Fig. 4c

5/6

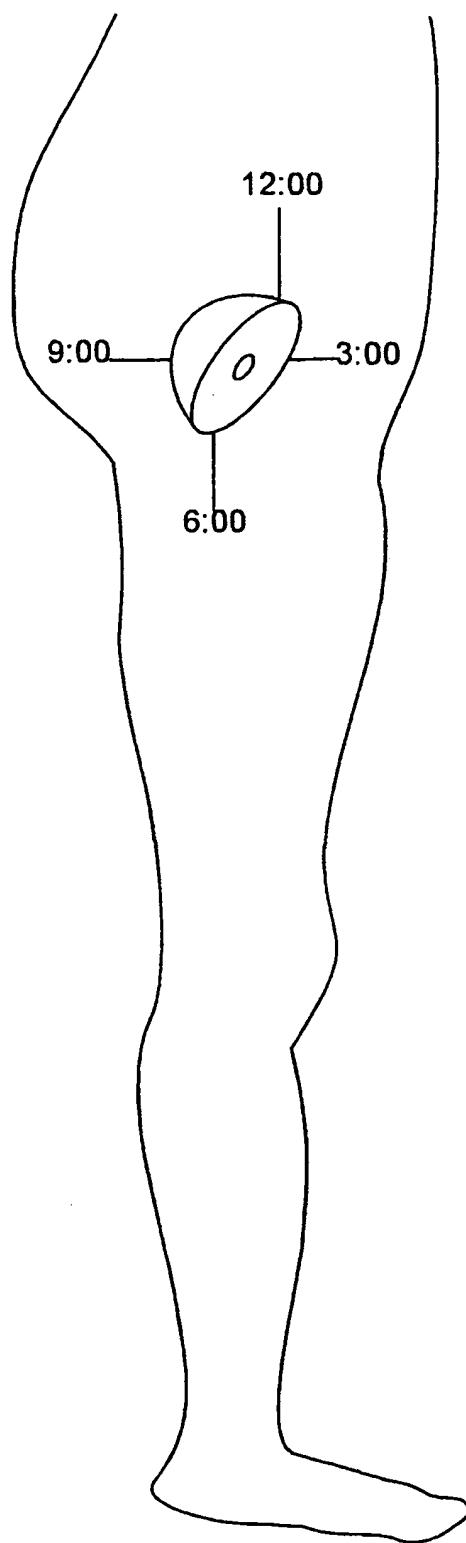


Fig. 5

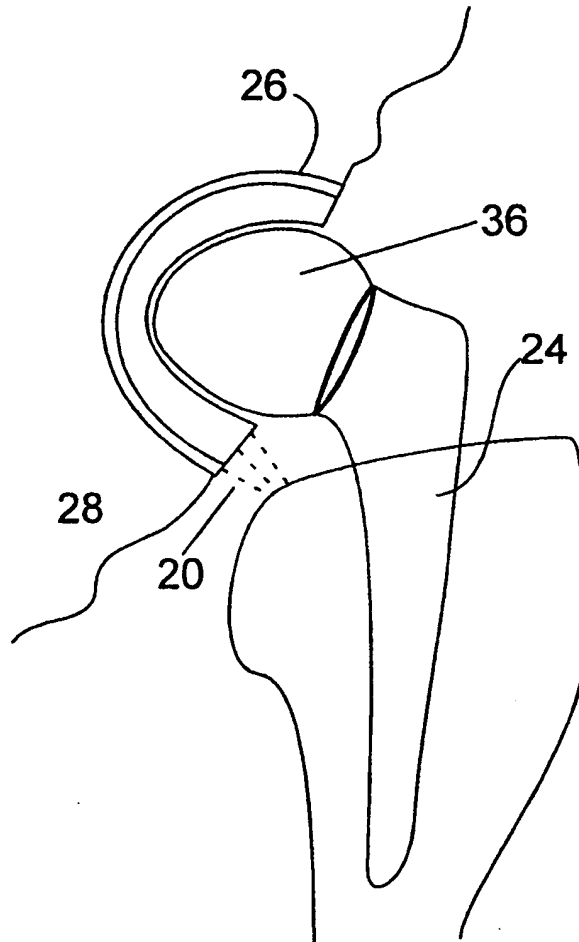


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/10994

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/34, 36

US CL : 623/22, 23

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/426; 623/22, 23

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P — Y	US 5,755,807 A (ANSTAETT et al.) 26 May 1998, col. 5, lines 26-47; col. 6, lines 17-19 and figure 2.	1-4, 8, 11-17, 21 and 22 ----- 5-7, 9, 10 and 18-20
Y	US 4,731,088 A (COLLIER) 15 March 1988, col. 5, lines 12-22.	5-7, 10 and 18-20
Y, P	US 5,916,585 A (COOK et al.) 29 June 1999, col. 4, lines 5-19.	9



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

09 JULY 1999

Date of mailing of the international search report

28 JUL 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

Hieu Phan

Telephone No. (703) 308-0858